

IN THE CLAIMS:

Please replace all previously pending claims with the listing of claims set forth below:

1-11. (Cancelled)

12. (Currently Amended) A process for preparing ~~an addition salt of azithromycin~~ hydrogen citrate in a solid state, according to Claim 1, comprising the steps of:

a) dissolving azithromycin monohydrate or dihydrate in a solvent or mixture of solvents to produce a solution;

b) adding citric acid in a molar ratio of the azithromycin to the citric acid close to the stoichiometric ratio to the solution to form the ~~addition salt~~ azithromycin hydrogen citrate salt; and

c) isolating the addition salt obtained by crystallization, comprising[.]

i) crystallising at a crystallization temperature between 25° C and the solvent's reflux temperature; and

ii) cooling the mixture to a temperature between 0° C and 25° C, before separating the crystals.

13. (Cancelled)

14. (Cancelled)

15. (Previously Presented) The process according to Claim 12, wherein the solvent is selected from the group consisting of water; the linear or branched C₁-C₆ aliphatic alcohols; cyclic aliphatic alcohols; diols; linear or branched C₁-C₆ aliphatic ketones; cyclic aliphatic ketones; short-chain aliphatic esters; short-chain aliphatic ethers; cyclic aliphatic ethers; and mixtures thereof.

16. (Previously Presented) The process according to Claim 12, wherein the solvent is selected from the group consisting of water, alcohols, ketones, esters, ethers, and mixtures thereof.

17-21. (Cancelled)

22. (Currently Amended) [[A]] The process for preparing an aqueous solution of solutions of an addition salt of azithromycin hydrogen citrate salt according to Claim 34 wherein, according to Claim 1,

a) the azithromycin hydrogen citrate salt is dissolved in water or water-alcohol mixtures containing up to 65% of said salt[.,]; and which comprises dissolving the azithromycin hydrogen citrate in water or water-alcohol mixtures and filtering the solution obtained.

b) the solution obtained is filtered.

23-25. (Cancelled)

26. (Currently Amended) A method for the therapeutic treatment of ~~an infection caused by bacteria or protozoans~~ bacterial or protozoan pathology in a mammal, comprising administering an effective amount of azithromycin hydrogen citrate salt according to Claim 34 to the patient requiring antibacterial or anti-protozoan therapy. ~~to a mammal in need thereof an effective amount of the addition salt of azithromycin according to Claim 1.~~

27-29. (Cancelled)

30. (Currently Amended) The process for preparing azithromycin hydrogen citrate salt addition salt of azithromycin according to Claim 29 ~~Claim 12, wherein the azithromycin hydrogen citrate salt obtained in step c) comprises further comprising up to 8% by weight of water.~~

31. (Currently Amended) The process for preparing azithromycin hydrogen citrate salt addition salt of azithromycin according to Claim 29 Claim 12, wherein the azithromycin hydrogen citrate salt obtained in step c) comprises further comprising up to 6% by weight of water.

32. (New) The process for preparing azithromycin hydrogen citrate salt according to Claim 12, wherein the azithromycin hydrogen citrate salt obtained in step c) comprises up to 3% by weight of residual solvent.

33. (New) The process for preparing azithromycin hydrogen citrate salt according to Claim 16, wherein the solvent is selected from the group consisting of water, ethanol, acetone, methyl acetate, tetrahydrofuran, and mixtures thereof.

34. (New) An azithromycin hydrogen citrate salt characterized by an X-ray diffraction spectrum, a carbon 13 nuclear magnetic resonance spectrum (^{13}C -NMR), and an IR spectrum recorded on KBr tablet shown on Figures 1 to 9.

35. (New) The azithromycin hydrogen citrate salt as prepared by the process of Claim 12, wherein the azithromycin hydrogen citrate salt has an X-ray diffraction spectrum, a carbon 13 nuclear magnetic resonance spectrum (^{13}C -NMR), and an IR spectrum recorded on KBr tablet shown on Figures 1 to 9.